REMARKS

Claims 1-18 are presently in the application.

The Examiner has required restriction under 35 U.S.C. 121 and 372.

It is urged that the application contains several inventions which are not linked to form a single general inventive concept under PCT Rule 13.1. Accordingly, restriction has been required from the following groups:

Group I, claims 1-10 and 14 which are drawn to a nucleic acid comprising a tissue specific promoter or fragment of that promoter, that selectively expresses carcinoma cells, a vector comprising the nucleic acid, a host cell comprising the nucleic acid and a medicament comprising the nucleic acid.

Group II, claim 11 which is drawn to an experimental animal comprising a cell which includes a nucleic acid having a tissue specific promoter that selectively expresses carcinoma cells.

Group III, claims 12, 13 and 15 drawn to a method for the treatment of cancer comprising administering to a patient a nucleic acid comprising a tissue specific promoter that selectively expresses carcinoma cells.

Group IV, claims 16-18 drawn to a method for evaluating a possible treatment of disease comprising testing such treatment on a host cell which comprises the

nucleic acid having a tissue specific promoter that selectively expresses carcinoma cells.

The requirement for restriction has been noted and is traversed as follows:

The Examiner has considered our prior remarks pertaining to the applicability of the Baptist et al reference as a basis for restriction and concluded that there was merit to our contention. At this juncture, the Examiner now relies upon the Chen et al reference as a basis for the new restriction requirement based upon the contention that this reference would negate the novelty of the claimed tumor specific promoter, thereby eliminating a common technical concept that would link the invention as a whole. Applicants take issue with this contention for the following reasons:

The common technical concept that would link the invention as a whole is the novel non-aqueous epithelial specific promoter. A tumor of non-squamous epithelial cells is indicated as a carcinoma. However, the term "carcinoma" is often incorrectly used to identify other tumor tissue cells, especially those of epithelial origin. Many cancers found in the human body are of epithelial origin. However, not all of them comprise non-squamous cells. Thus, for example, glandular epithelial tumors have a different phenotype than non-aqueous epithelial tumors. Additionally, cancers of other origins than epithelium are called non-squamous tumors.

In the instant case, the promoter is specific for the non-squamous epithelial tumor cells, such cells being a subgroup of the epithelial tumor cells which may also be considered a subgroup of all tumor cells.

A further review of the Chen et al reference reveals that the language "carcinoma specific" is used in a broad sense and that the DF3/MUC1 promoter alluded to cannot be considered to be non-squamous epithelial specific. Furthermore, it is recognized by those skilled in the art that the DF3/MUC1 promoter is not specific for non-squamous epithelial tumors.

Applicants are transmitting herewith a copy of a publication by Cooper et al (Br. J. Dermatology (2004) 25 (4):1119-1126 which describes the expression of Muc1 as being detected in 100% of SCCa (cutaneous squamous cell carcinoma) thereby indicating that MUC1 is not only expressed in non-squamous cell carcinomas. Additionally, specificity can exist(as with EGP-2) if expression takes place in all carcinoma cells. Abe et al in Proc. Natl. Acad. Sci. USA 90:282-286 report that the DF3 gene is abundant in malignant mammillary epithelium. It is reported to be expressed in approximately 75% of primary breast carcinomas. Since it is known that less that 99% of the breast carcinomas are of non-squamous origin, it is evident that at least one quarter of these non-squamous carcinomas do not express MUC1/DF3. In light of this, it is crystal clear that the carcinoma specific promoter of Chen et al does not meet the requirements for specificity.

Accordingly, it is urged that the requirement for restriction is in error and it is requested that it be withdrawn.

In order to comply with the Examiner's requirement for restriction, applicants provisionally elect Group I drawn to a nucleic acid comprising a tissue specific promoter or a fragment of that promoter which selectively expresses carcinoma cells, a vector comprising the nucleic acid, a host cell comprising the nucleic acid and a medicament comprising the nucleic acid. Claims 1-10 and 14 are readable thereon.

Reconsideration of the Examiner's Requirement for Restriction is most earnestly solicited.

Respectfully submitted,

November 5, 2004

Peter L. Michaelson, Attorney
Reg. No. 30,090
Customer No. 007265
(732) 530-6671

MICHAELSON & ASSOCIATES
Counselors at Law
Parkway 109 Office Center
328 Newman Springs Road
P.O. Box 8489
Red Bank, New Jersey 07701

Appl. No. 10/009,579
Amdt. dated Nov. 5, 2004
Reply to Office Action of Sept. 7, 2004

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